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Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: An Updated Systematic Review and Meta-analysis of Effectiveness and Complications

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Abstract

Context: An updated systematic review and meta-analysis of randomised controlled trials (RCTs) comparing single-incision mini-slings (SIMS) versus standard midurethral slings (SMUS) in the surgical management of female stress urinary incontinence (SUI).
Objective: To evaluate the clinical efficacy, safety, and cost effectiveness of SIMS compared with SMUS in the treatment of female SUI.
Evidence acquisition: A literature search was performed for all RCTs and quasi-RCTs comparing SIMS with either transobturator tension-free vaginal tape (TO-TVT) or retropubic tension-free vaginal tape (RP-TVT). The literature search had no language restrictions and was last updated on May 2, 2013. The primary outcomes were patient-reported and objective cure rates at 12 to 36 mo follow-up. Secondary outcomes included operative data; peri- and postoperative complications, and repeat continence surgery. Data were analysed using RevMan software. Meta-analyses of TVT-Secur versus SMUS are presented separately as the former was recently withdrawn from clinical practice.
Evidence synthesis: A total of 26 RCTs (n = 3308 women) were included. After excluding RCTs evaluating TVT-Secur, there was no evidence of significant differences between SIMS and SMUS in patient-reported cure rates (risk ratio [RR]: 0.94; 95% confidence interval [CI], 0.88–1.00) and objective cure rates (RR: 0.98; 95% CI, 0.94–1.01) at a mean follow-up of 18.6 mo. These results pertained on comparing SIMS versus TO-TVT and RP-TVT separately. SIMS had significantly lower postoperative pain scores (weighted means difference [WMD]: −2.94; 95% CI, −4.16 to −1.73) and earlier return to normal activities and to work (WMD: −5.08; 95% CI, −9.59 to −0.56 and WMD: −7.20; 95% CI, −12.43 to −1.98, respectively). SIMS had a nonsignificant trend towards higher rates of repeat continence surgery (RR: 2.00; 95% CI, 0.93–4.31).
Conclusions: This meta-analysis shows that, excluding TVT-Secur, there was no evidence of significant differences in patient-reported and objective cure between currently used SIMS and SMUS at midterm follow-up while associated with more favourable recovery time. Results should be interpreted with caution due to the heterogeneity of the trials included.

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1. Introduction

Since our last systematic review and meta-analysis in 2011 [1], Professor Peter Petros updated us that he first introduced the first single-incision mini-sling (SIMS: Tissue Fixation System [TFS]) in September 2003 (pers. comm., P. Petros, Perth, Australia). Since then different types of devices have been designed and used in clinical practice. SIMS have a number of potential advantages that attracted the attention of many surgeons worldwide: (1) shorter length polypropylene tape and therefore less mesh to be inserted into the human body; (2) insertion through a single vaginal incision to create a similar suburethral hammock to standard midurethral slings (SMUS) while avoiding both retropubic and groin trajectories (in retropubic tension-free vaginal tape [RP-TVT] and transobturator tension-free vaginal tapes (TO-TVT), respectively); and (3) the ability to perform the procedure under pure local anaesthesia (LA) and therefore a shorter recovery and earlier return to work/normal activities [2]. These potential advantages, if proven, may be reflected in improving women's quality of life (QoL) and potential cost savings to health providers and society. However, the advantages just cited would be only relevant if SIMS are proven to have a similar or at least noninferior clinical efficacy compared with SMUS.

In an earlier systematic review and meta-analysis in 2011 [1], we showed that SIMS did not, at least at that stage, live up to their potential, and we recommended they only be used within the context of research. Over the last 2 yr, >20 randomised controlled trials (RCTs) comparing SIMS with SMUS were further reported, and additionally a number of RCTs published their longer-term follow-up. A significant event occurred when an extensively researched SIMS (TVT-Secur) was withdrawn from clinical practice by the manufacturer [3], having been shown to have poor clinical outcomes at the midterm follow-up [4–7]. This situation emphasises the importance of mid- to long-term follow-up of new technologies before they are adopted into clinical practice.

Following the Cochrane recommendation, we present this updated systematic review >2 yr since our last review. In this update we look at RCTs comparing SIMS with SMUS with a 12 to 36 mo follow-up. We aim to present clinically relevant results with the meta-analyses of TVT-Secur versus SMUS presented separately. In-addition, we present a subgroup analysis of the relatively new, adjustable and robustly anchored SIMS versus SMUS.

2. Evidence acquisition

An updated meta-analysis was performed per the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement guidance [8]. All RCTs and quasi-RCTS comparing one type of SIMS versus a SMUS in the surgical treatment of women with stress urinary incontinence (SUI), with a minimum follow-up of 12 mo, were eligible for inclusion. These included women with urodynamic or clinical diagnosis of SUI with or without symptoms of overactive bladder and with or without concomitant prolapse surgery. SMUS in this review included RP-TVT and TO-TVT (inside-out and outside-in); SIMS were defined as a midurethral sling performed through a single vaginal incision with no entry or exit skin incisions.

The literature search was last updated on May 2, 2013, using the Medline and Embase databases. Trials registered in the ClinicalTrials.gov, Australian or Netherlands clinical trials registry, World Health Organisation database, and Cochrane database of systematic reviews were searched. A manual search of the abstract databases of international conferences was performed including the International Continence Society, European Association of Urology, and the International Urogynaecology Association conferences. In addition, a hand search of bibliographies of the primary articles and relevant reviews was performed. No language restriction or publication types were applied, and search criteria were limited to humans, adult females, and entry date from 1996. The search was performed independently by two authors (A.M. and C.P.L.) and included Medical Subject Heading subheadings, word variations, and free text: *TVT Secur™, Mini tape, Ophira®, Contasure, Needleless, Solyx™, Mini arc™, Ajust®, Mini Sling, Zippere, Epilog, Altis®*, and *Tissue fixation system*. Figure 1 outlines the steps for the Ovid Medline and Embase database search. All identified studies were screened for eligibility, in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* [9] and independently assessed by two authors (A.M. and C.P.L.). Table 1 shows a list of the included RCTs.

Similarly, data extraction was independently performed by three authors (A.M., C.P.L., and L.H.) followed by cross-checking and clarification of any differences by the senior author (M.A.F.). Non-English articles were translated. All authors of included studies were contacted for missing data and data on longer follow-up durations if applicable. The quality of the retrieved RCTs was assessed using the Jadad score [10]. Risk of bias across studies was assessed according to the *Cochrane Handbook for Systematic Reviews* [9] and generated through RevMan software. Table 2 shows the list of excluded studies (n = 32) and the reasons for exclusion.

The primary outcomes assessed were the subjective (patient-reported) and objective cure/improvement rates. Secondary outcomes included operative data (duration of operation, length of inpatient stay, time to return to normal activity); perioperative complications (eg, organ injuries); postoperative complications (voiding dysfunction/intermittent self-catheterisation, postoperative pain scores, de novo detrusor overactivity, de novo urgency, tape erosion); repeat surgery for SUI; impact on women's QoL, sexual function, and costs to health services. Analysis was performed for comparing the primary outcomes in individual types of SIMS versus different types of SMUS, with a subgroup meta-analysis of the relatively new, robustly anchored and adjustable SIMS (Ajust and TFS) versus SMUS. Meta-analyses of TVT-Secur versus SMUS is presented separately being the least clinically relevant.

Data were analysed using RevMan v.5.2.20 (Cochrane Collaboration, Oxford, UK). Quantitative synthesis was done when more than one eligible study was identified. Where appropriate, a combined estimate of treatment effect across

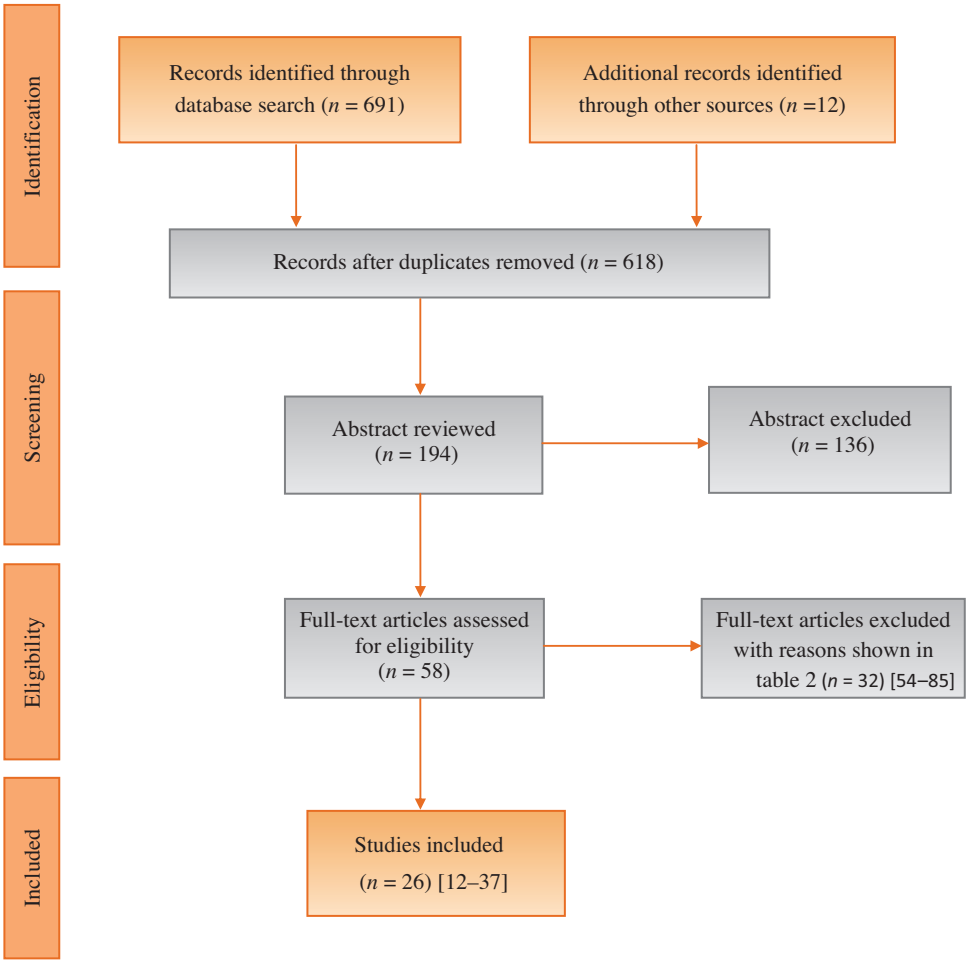


Fig. 1 – Preferred Reporting Items for Systematic Reviews and Meta-analysis.

similar studies was calculated for each prespecified outcome. The results were expressed as weighted means difference (WMD), standard deviations (SDs) for continuous outcomes, and risk ratio (RRs) with 95% confidence intervals (CIs) for dichotomous variables using the Mantel-Haenszel method [9]. Methodological heterogeneity was assessed during selection, and statistical heterogeneity was measured using the chi-square test and I^2 scores. A random-effects model [11] was used throughout to reduce the effect of statistical heterogeneity. Then 24-mo data were extracted from studies where possible to improve methodological heterogeneity; otherwise, 12- or 36-mo data were used. Sensitivity analysis was performed for primary outcomes by excluding RCTs with unclear quality.

3. Evidence synthesis

Figure 1 describes the literature search outcome according to the PRISMA flowchart. A total of 26 RCTs including 3308 women (SMUS: $n = 1573$ vs SIMS: $n = 1735$) were included in this updated meta-analysis. These RCTs assessed different SIMS: Mini-arc (7 RCTs; $n = 759$) [12–18], SIMS-Ajust (3 RCTs; $n = 350$) [19–21], Ophira (1 RCT; $n = 130$) [22], Contasure-Needleless (1 RCT; $n = 257$) [23], SIMS-TFS (1 RCT; $n = 80$) [24], Solyx (1 RCT; $n = 30$) [25], and TVT-Secur (12 RCTs; $n = 1606$) [26–37]. SIMS were compared with RP-TVT in 4 RCTs [18,25,34,35] and TO-TVT in 22 RCTs [12–17,19–24,26–33,36,37]. All authors were contacted, and supplementary data were provided by 17 authors; a number of authors provided the 24-mo data for their published longer or shorter follow-up reports [20,21,23–25]. Otherwise, 12- or 36-mo data were used as available with preference given to longer-term follow-up if both data sets were available for the same RCT [13,18,37]. Two RCTs were translated, from Dutch [12] and from Russian [29]; 32 studies were excluded (Table 2). Overall, 259 women (7.8%) were lost to follow-up (SMUS: $n = 117$ vs SIMS: $n = 142$). The mean age (SMUS: 55.27 yr vs SIMS: 50.88 yr), mean body mass index (SMUS: 24.98 vs SIMS: 24.80 kg/m^2), and median parity (SMUS: 2 vs SIMS: 2) were comparable. Mean for the follow-up of the included studies was 18.62 mo (standard deviation: ±9.2; range:12–36 mo).

3.1. *Patient-reported and objective cure rate*

A total of 21 RCTs reported patient-reported and objective cure rates. Meta-analyses showed that on excluding RCTs for TVT-Secur ($n = 10$), there was no evidence of significant

Table 1 – Detailed summary of included studies

Study	Design	Participant	Intervention: SIMS	Comparison: SMUS	Outcomes and follow-up duration	Definition of patient-reported cure	Definition of objective cure	Hypothesis/objectives
Enzelsberger et al. [12]	Quasi-randomised single-centre RCT Austria	95 women Inclusion criteria: positive stress test, or subjective experience of SUI Loss to FU: 5 women	Mini-Arc *n* = 47	TO-TVT *n* = 48	Objective cure rate at 24-mo FU Postoperative pain at 48 h Length of operation and complications	N/A	Negative CST with bladder volume 250 ml	To compare the efficacy of Mini-Arc vs TO-TVT
Oliveira et al. [13]	Randomised single-centre trial Portugal	60 women Inclusion criteria: women with clinically and urodynamically proven SUI with urethral hypermobility Lost to FU: 11 women	Mini-Arc *n* = 30	TO-TVT *n* = 30	Objective and patient-reported cure at 24-mo FU QoL and sexual function symptom severity and postoperative pain	Reported no episodes of leakage and ceased to wear incontinence protection	NA	Exploratory study to assess the differences in efficacy between Mini-Arc and TO-TVT
Merali et al. [14]	Randomised single-centre RCT Canada	37 women Inclusion criteria: all women with stress urinary incontinence No loss to FU	Mini-Arc *n* = 18	TO-TVT *n* = 19	Objective cure at 12-mo postoperative complications	N/A	Negative 1-h pad test	To compare the objective cure rates between the Mini-Arc and TO-TVT in women with SUI
Tieu et al. [15]	Randomised single-centre study USA	98 women Inclusion criteria: urodynamically proven SUI Lost to FU: 15 women	Mini-Arc *n* = 49	TO-TVT *n* = 49	Objective and subjective cure at 12-mo FU intraoperative and postoperative complications QoL	Subjective reports of no SUI, self-assessment of cure, and response to validated questionnaires	Negative CST	To compare 1-yr surgical outcomes of transobturator with single-incision slings for the treatment of SUI
Schellart [16]	Randomised multicentre The Netherlands	193 women Inclusion criteria: all women with urodynamic SUI	Mini-Arc *n* = 97	TO-TVT *n* = 96	Subjective and objective cure at 12-mo operation time, morbidity and reinterventions	Responding with "no" or "slightly bothered" to the question: "Are you bothered by urinary incontinence during physical activity like coughing or sneezing?"	Negative CST with at least 300 ml bladder filling	To compare subjective and objective cure, morbidity, and discomfort following Mini-Arc and TO-TVT in women with SUI
Lee et al., [17]	Randomised multicentre RCT Australia	224 women Inclusion criteria: women with SUI or USI age ≥18 yr Loss to FU: 19 women	Mini-Arc *n* = 112	TO-TVT *n* = 112	Objective cure rate and patient-reported success at 12-mo FU sexual function using symptom severity	Reported absence of patient-reported SUI	Negative urodynamic stress or CST	To compare objective, subjective, and functional outcomes after Mini-Arc or TO-TVT in women with SUI at 12 mo
Basu et al. [18]	Randomised single-centre UK	71 women Inclusion: women with SUI symptoms and objective evidence of SUI, failed conservative treatment, suitable for a continence procedure Loss to FU: 10 women	Mini-Arc *n* = 38	RP-TVT *n* = 33	Subjective cure rate at 36-mo FU Secondary continence procedures QoL	Reported absence of SUI symptoms on direct questioning and on the relevant KHQ domain	NA	Evaluation of the efficacy of the mini-sling vs RP-TVT
Mostafa et al. [19]	Randomised multicentre UK	137 women Inclusion criteria: women with SUI, had failed or declined PFMT, undergoing a primary continence procedure, and have the ability to understand the information leaflet Loss to FU: 6 women	SIMS-Ajust *n* = 69	TO-TVT *n* = 68	Objective and patient-reported cure at 12-mo FU Operative details and postoperative complications QoL and sexual function Economic evaluation	Responses of "Very much improved/much improved" on PGI-I	Negative CST with comfortably full bladder	To evaluate the SIMS-Ajust and compare it with TO-TVT
Schweitzer et al. [20]	Randomised single-centre RCT The Netherlands	156 women Inclusion criteria: women with SUI, completed conservative therapy, Sandvik >3, good knowledge of Dutch Loss to FU: 13 women	SIMS-Ajust *n* = 100	TO-TVT *n* = 56	Patient-reported success and objective cure rate at 12-mo FU Postoperative pain at 1 wk and 6 wk Improvement of symptoms on UDI Length of operation Complications	Response: "No" to question regarding SUI on UDI	NA	To compare the efficacy of mini-slings with that of transobturator tapes

Table 1 (*Continued*)

Study	Design	Participant	Intervention: SIMS	Comparison: SMUS	Outcomes and follow-up duration	Definition of patient-reported cure	Definition of objective cure	Hypothesis/objectives
Dati et al. [21]	Randomised single-centre RCT Italy	115 women Inclusion criteria: all women with urodynamic SUI Lost to FU: 1 woman	SIMS-Ajust *n* = 57	TO-TVT *n* = 58	Objective, subjective cure at 12-mo FU Postoperative complications and postoperative pain QoL	N/A	Negative CST	To compare the efficacy, safety, and complications of SIMS-Ajust vs TO-TVT in the management of female SUI
Djehdian et al. [22]	Randomised single-centre Brazil	130 women Inclusion criteria: women with SUI and no prolapse higher than stage 1 Loss to FU: 10 women	Ophira *n* = 69	TO-TVT *n* = 61	Objective cure at 12-mo FU QoL, postoperative complications	Answer of "Yes" to patient satisfaction	1-h pad test with a gain of <2 g and negative CST	To compare the efficacy and safety of the mini-sling Ophira and TO-TVT in women with SUI
Amat i Tardiu et al. [23]	Quasi-randomised single-centre Spain	275 women Inclusion criteria: patients with SUI and positive stress test, with or without associated genital prolapse, candidates for surgical treatment Lost to FU: 31 women	Needleless-Contasure *n* = 157	TO-TVT *n* = 118	Patient-reported satisfaction, objective cure at 24 mo Symptom severity on ICIQ postoperative complications	Subjective impression of the treatment received through a direct question on satisfaction of the results of the intervention; very satisfied, satisfied or dissatisfied	Negative CST	Noninferiority study hypothesising that the single-incision sling is not inferior to the transobturator inside-out
Sivaslioglu et al. [24]	Randomised single-centre Turkey	80 women Inclusion criteria: patients with SUI and first-time incontinence surgery, conservative treatment failed Lost to FU: 2 women	TFS *n* = 40	TO-TVT *n* = 40	Objective cure and patient-reported subjective cure at 24-mo FU Operation length, postoperative groin pain, mesh extrusion, and urinary retention	Patient reported restoration of continence	Negative CST	To assess the efficacy of TFS in women with SUI compared with that of the TO-TVT
Gopinath et al. [25]	Randomised single-centre RCT UK	30 women Inclusion criteria: all women with urodynamic stress urinary incontinence Lost to FU: 1 woman	Solyx *n* = 15	RP-TVT *n* = 15	Subjective cure at 12 mo Postoperative pain Time to return to driving	Response of "very much better/much better" on PGI-I	24-h pad test with <4-g gain	To compare the efficacy of Solyx vs TO-TVT
Friedman et al. [26]	Randomised single-centre Israel	84 women Inclusion criteria: women with SUI, indications for operative treatment, positive stress test No loss to FU	TVT-Secur *n* = 42	TO-TVT *n* = 42	Patient-reported success and objective cure at 12-mo FU Postoperative complications	Patient's report of complete resolution of symptoms during physical activities or increased intraabdominal pressure or significant improvement in previous complaints	NA	To compare the TO-TVT and TVT-S in terms of intraoperative complications, perioperative morbidity, and efficacy at 1 yr in women with SUI
Tommaselli et al. [27]	Randomised single-centre RCT Italy Equivalency design	84 women Inclusion criteria: women with SUI for at least 2 yr, diagnosed clinically and by urodynamics, age >40 yr Lost to FU: 9 women	TVT-Secur *n* = 42	TO-TVT *n* = 42	Objective cure rate at 12-mo FU Length of operation, length of hospital stay Postoperative complications: blood loss, pain, patient satisfaction QoL, symptoms severity ICIQ-SF	N/A	Completely continent during CST and during exertion required for urodynamics	Comparison of TVT-S vs TO-TVT in terms of efficacy and safety
Hinoul et al. [28]	Randomised multicentre Belgium and the Netherlands	195 women Inclusion criteria: women with clinical or urodynamic diagnosis of SUI Lost to FU: 30 women	TVT-Secur *n* = 97	TO-TVT *n* = 98	Objective cure rate and patient-reported cure at 12-mo FU Postoperative pain, QoL, urgency, and urgency incontinence	Subjective reporting of SUI (response to whether any episodes of SUI had occurred during the last month)	Negative CST with bladder volume of 300 ml	To compare the efficacy and morbidity of SIMS vs TO-TVT
Pushkar et al. [29]	Randomised single-centre Russia	95 women Inclusion criteria: women with primary SUI or MUI with predominant stress, age >18 yr, positive CST Lost to FU: 3 women	TVT-Secur *n* = 45	TO-TVT *n* = 50	Objective and subjective cure rate at 12 mo Postoperative complication rates QoL	Reported of 8–10 points on patient-reported severity of incontinence scale	Negative CST with bladder volume 150 ml	To compare the efficacy of TVT-Secur vs TO-TVT

Wang et al. [30]	Randomised multicentre RCT China	70 women Inclusion criteria: women with SUI No lost to FU	TVT-Secur $n = 34$	TO-TVT $n = 36$	Objective and subjective cure rates at 12 mo Length of operation, intraoperative and postoperative complications	Patient reported absence of urinary leakage	Negative CST	Evaluation and comparison of TVT, TVT-O, and TVT-S
Lee et al. [31]	Randomised South Korea	122 women Inclusion criteria: women with urodynamic SUI	TVT-Secur $n = 62$	TO-TVT $n = 60$	Objective cure (CST) and subjective cure at 24-mo FU QoL, patient satisfaction	Reported absence of involuntary leakage during stressful activities and no pad use	Negative CST	Compare the efficacy and patient satisfaction between TO-TVT and TVT-S in women with SUI
Masata et al. [32]	Randomised single-centre Czech Republic	197 women Inclusion criteria: women with urodynamic SUI, failed conservative therapy, >18 yr and agreed to postoperative follow-up No lost to FU	TVT-Secur $n = 129$	TO-TVT $n = 68$	Objective cure rate and subjective cure rate at 24-mo FU Pain on VAS, QoL, urgency rates	No leakage reported on ICIQ-SF on questions regarding leakage during physical exercise and leakage when coughing/sneezing	Negative CST	To compare the efficacy of TO-TVT vs TVT-S in women with SUI
Hota et al. [33]	Randomised single-centre USA	87 women Inclusion criteria: women with SUI with an impact on QoL, positive CST during urodynamics Lost to FU: 1 woman	TVT-Secur $n = 43$	TO-TVT $n = 44$	Objective failure at 12 mo QoL and symptom severity Postoperative pain, mesh erosion, intraoperative blood loss, length of procedure	N/A	Negative CST	Comparison of TVT-S and TO-TVT for treatment of SUI
Barber et al. [34]	Randomised multicentre RCT USA	264 women Inclusion criteria: women at least 21 yr of age with USI on multichannel urodynamics, desire for surgical treatment, concurrent surgical treatment of prolapse Lost to FU: 7 women	TVT-Secur $n = 136$	RP-TVT $n = 127$	Subjective cure at 12 mo Postoperative pain and complications Impact on sexual function and QoL	Reported absence of urinary incontinence as indicated by an Incontinence Severity Index score of 0	NA	To compare the efficacy of SIMS vs RP-TVT in the treatment of SUI
Andrada Hamer et al. [35]	Randomised multicentre Sweden	133 women Inclusion criteria: primary SUI or MUI with predominant stress, >18 yr of age and no wish for further pregnancy, ≥3 ml leakage on pad test, positive CST Lost to FU: 12 women	TVT-Secur $n = 64$	RP-TVT $n = 69$	Subjective and objective cure rate at 12-mo FU Postoperative complications	Reported cured or improved for stress incontinence symptoms	Negative CST	Comparison of RP-TVT vs TVT-S in terms of efficacy and safety
Tommaselli et al. [36]	Randomised multicentre Italy	154 women Inclusion criteria: women with SUI, diagnosed clinically and by urodynamics, age >30 yr, failed PFMT Lost to FU: 24 women	TVT-Secur $n = 77$	TO-TVT $n = 77$	Objective cure rate at 36-mo FU QoL sexual function Patient-reported symptom postoperative complication rates	Patient reported no urinary leakage	Negative CST	To compare the efficacy of TO-TVT vs TVT-S at 36 mo
Bianchi-Ferraro et al. [37]	Randomised single-centre Brazil	22 women Inclusion criteria: women with SUI without detrusor overactivity, no concomitant prolapse ≥2 POP-Q Lost to FU: 7 women	TVT-Secur $n = 66$	TO-TVT $n = 56$	Objective and subjective cure at 24-mo QoL, rates of postoperative complications	Reported absence of urinary leakage indicated by the KHQ symptom scale score of 0	Negative pad test and CST	TVT-S is not inferior to TO-TVT for treatment of SUI, and to compare the efficacy and complications of TVT-O vs TVT-S as surgical treatment for SUI

CST = cough stress test; FU = follow-up; ICIQ-SF: International Consultation of Incontinence Questionnaire-Short Form; MUI = mixed urinary incontinence; NA = not applicable; PFMT = pelvic floor muscle training; POP-Q = Pelvic Organ Prolapse Quantification; QoL = quality of life; RP-TVT = retropubic tension-free vaginal tape; SIMS = single-incision mini-sling; SMUS = standard midurethral sling; SUI = stress urinary incontinence; TO-TVT = transobturator tension-free vaginal tape; USI = urinary stress incontinence; VAS = visual analogue scale.

Table 2 – Summary of excluded studies

Study	Reason for exclusion	Study	Reason for exclusion
Abdelwahab et al. [54]	RCT/Outcome <12-mo FU	Ross and Schulz [55]	Ongoing RCT
Masata et al. [56]	RCT/Outcome <12-mo FU	Foote [57]	Ongoing RCT
Kim et al. [58]	RCT/Outcome <12-mo FU	Maslow [59]	Ongoing RCT
Yoon et al. [60]	RCT/Outcome <12-mo FU	Poza [61]	Ongoing RCT
De Ridder et al. [62]	Retrospective study	Dias et al. [63]	RCT comparing two approaches for SIMS insertion
Fatima et al. [64]	Retrospective study	Palomba et al. [65]	RCT comparing three types of SIMS
Abdul-Jabbar et al. [66]	Retrospective study	Kim et al. [67]	RCT comparing two approaches for SIMS insertion
Charalambous et al. [68]	Retrospective study	Tommaselli et al. [69]	RCT comparing two approaches for SMUS insertion
Stavros et al. [70]	Retrospective study	Pardo et al. [71]	RCT comparing two types of SIMS
Chakrabarty et al. [72]	Retrospective study	Seo et al. [73]	RCT comparing two approaches for SIMS insertion
Sun et al. [74]	Retrospective study	Meschia et al. [75]	RCT comparing two types of SIMS
Brown et al. [76]	Retrospective study	Smith et al. [77]	Comparative study
Kim et al. [78]	Retrospective study	O'Donovan et al. [79]	Comparative study
Arianna et al. [80]	Comparative study	Bianchi et al. [81]	Comparative study
Naumann et al. [82]	Comparative study	Jeong et al. [83]	Comparative study
Neuman et al. [84]	Comparative study	Hwang et al. [85]	Comparative study

FU = follow-up; RCT = randomised controlled study; SIMS = single-incision mini-sling; SMUS = standard midurethral sling.

differences in patient-reported cure (RR: 0.94; 95% CI, 0.88–1.00) and objective cure (RR: 0.98; 95% CI, 0.94–1.01) for SIMS versus SMUS at a mean follow-up of 18.6 mo (Fig. 2a and 2b); trends towards more favourable outcomes in the SMUS group were noted. These results pertained to comparing SIMS versus TO-TVT (patient-reported cure: RR: 0.96; 95% CI, 0.92–1.00, and objective cure: RR: 0.98; 95% CI, 0.94–1.01) and versus RP-TVT (patient-reported cure: RR: 0.71; 95% CI, 0.42–1.20, and objective cure: RR: 0.81; 95% CI, 0.48–1.40) (Fig. 2c and 2d). These results also pertained to sensitivity analysis including high-quality RCTs only (Supplemental Fig. 1 and 2). An exploratory subgroup meta-analysis of RCTs ($n = 4$) evaluating the relatively new robustly anchored adjustable SIMS (Ajust and TFS) versus SMUS showed promising results in patient-reported cure rate (RR: 1.09; 95% CI, 0.91–1.31) and objective cure rate (RR: 1.01; 95% CI, 0.92–1.10) (Supplemental Fig. 3 and 4). Looking at individual types of SIMS; it was evident that Ophira had a significantly lower objective cure rate when compared with SMUS (Fig. 2b), whereas Mini-arc showed a nonsignificant trend towards poor patient-reported cure rates (Fig. 2a). Meta-analysis of RCTs evaluating TVT-Secur versus SMUS showed that TVT-Secur had inferior patient-reported and objective cure rates at a mean follow-up of 17.4 mo (RR: 0.86; 95% CI, 0.81–0.91, and RR: 0.81; 95% CI, 0.75–0.88, respectively) (Fig. 2e and 2f). A nonsignificant trend towards higher rates of repeat continence surgery was noted in the SIMS group (RR: 2.00; 95% CI, 0.93–4.31).

3.2. *Quality of life and sexual function*

A total of 13 RCTs reported QoL changes. Meta-analysis was possible for three RCTs [15,19,24] that used validated questionnaires with same interpretability scores (Incontinence Impact Questionnaire–Short Form IIQ-7 [38] and King's Health Questionnaire-7 [39]) and showed no evidence of significant differences in QoL scores between both groups (WMD: 1.23; 95% CI, −2.76 to 5.21) (Fig. 3a). Other RCTs used validated questionnaires but were either reported as median (interquartile range) [17,18,33] or presented their results scores in graphs or total scores [13,21,36], and therefore meta-analyses was not possible. Nevertheless, all RCTs reported improvement in QoL scores at the follow-up compared with baseline with no significant differences between SIMS versus SMUS. Five RCTs reported the impact on sexual function; meta-analysis was possible for two studies [19,20] that used the same questionnaire, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) [40]. There was no evidence of significant differences in total PISQ-12 scores between both groups (WMD 0.39; 95% CI, −0.89 to 1.67) (Fig. 3b).

3.3. *Operative data and complications*

On exclusion of RCTs that evaluated TVT-Secur, SIMS were associated with significantly shorter operative time (WMD: −2.95 min; 95% CI, −5.02 to −0.88, Fig. 4a), lower postoperative pain scores (WMD: −3.13; 95% CI, −4.89 to −1.36; Fig. 4b), earlier return to normal activities (WMD: −5.08; 95% CI, −9.59 to −0.56; Fig. 4c), and earlier return to work (WMD: −7.20; 95% CI, −12.43 to −1.98; Fig. 4d). Figure 5 demonstrates the meta-analysis of perioperative complications and various adverse events. After excluding trials with TVT-Secur, there was no statistically significant difference in the rate of lower urinary tract injury, postoperative voiding difficulties, vaginal tape erosions, de novo urgency, and/or worsening of preexisting urgency. Also the groin pain rate was significantly lower in the SIMS group (RR: 0.30; 95% CI, 0.18–0.49). Figure S5 compares complications between SIMS (excluding TVT-Secur) versus RP-TVT and TO-TVT separately.

3.4. *Health economic evaluation*

In one RCT, SIMS-Ajust performed under LA, as an opt-out policy, delivered cost savings to the health service provider when compared with the SMUS TVT-O and was likely to be more cost effective with up to 1-yr follow-up [41].

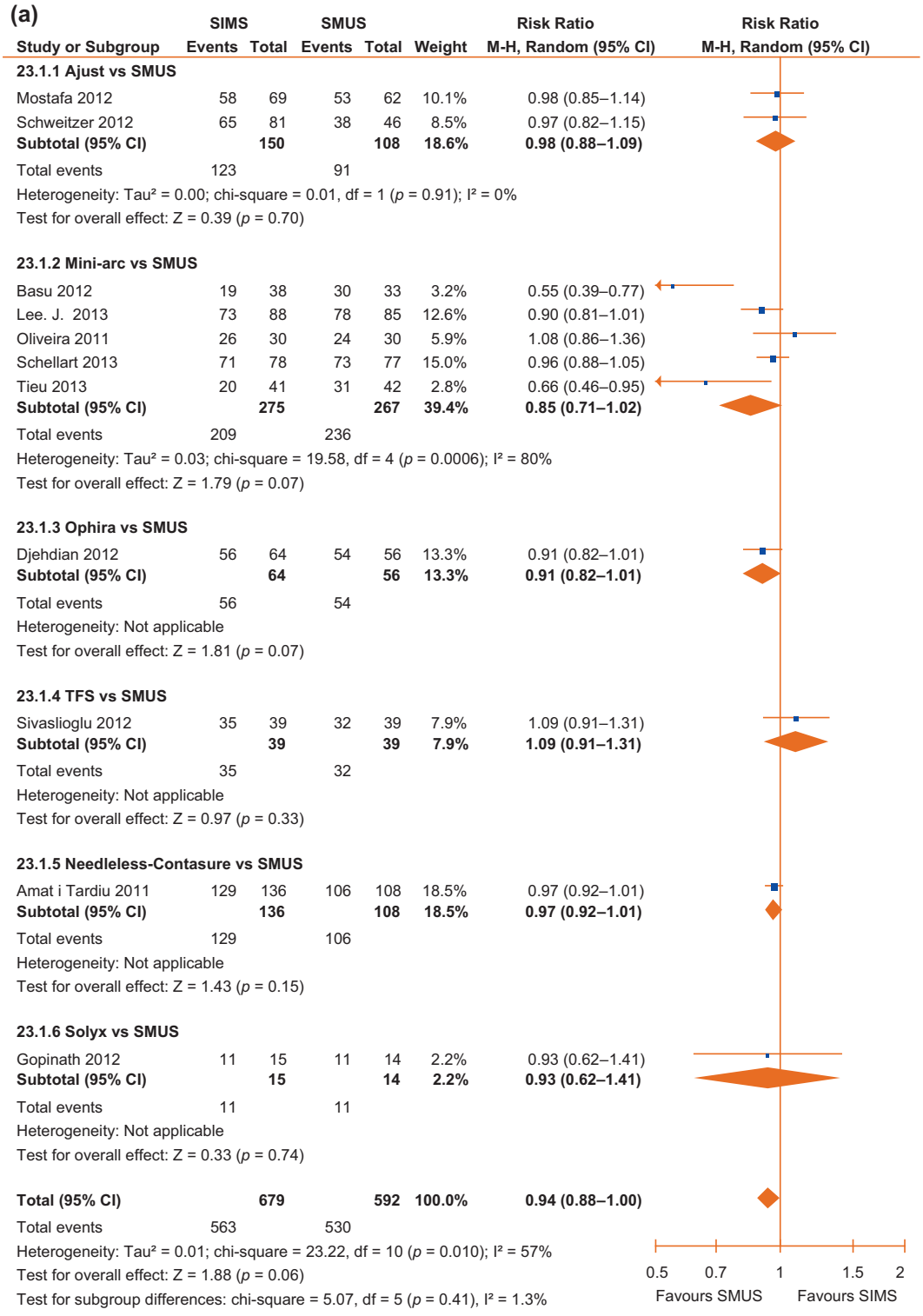
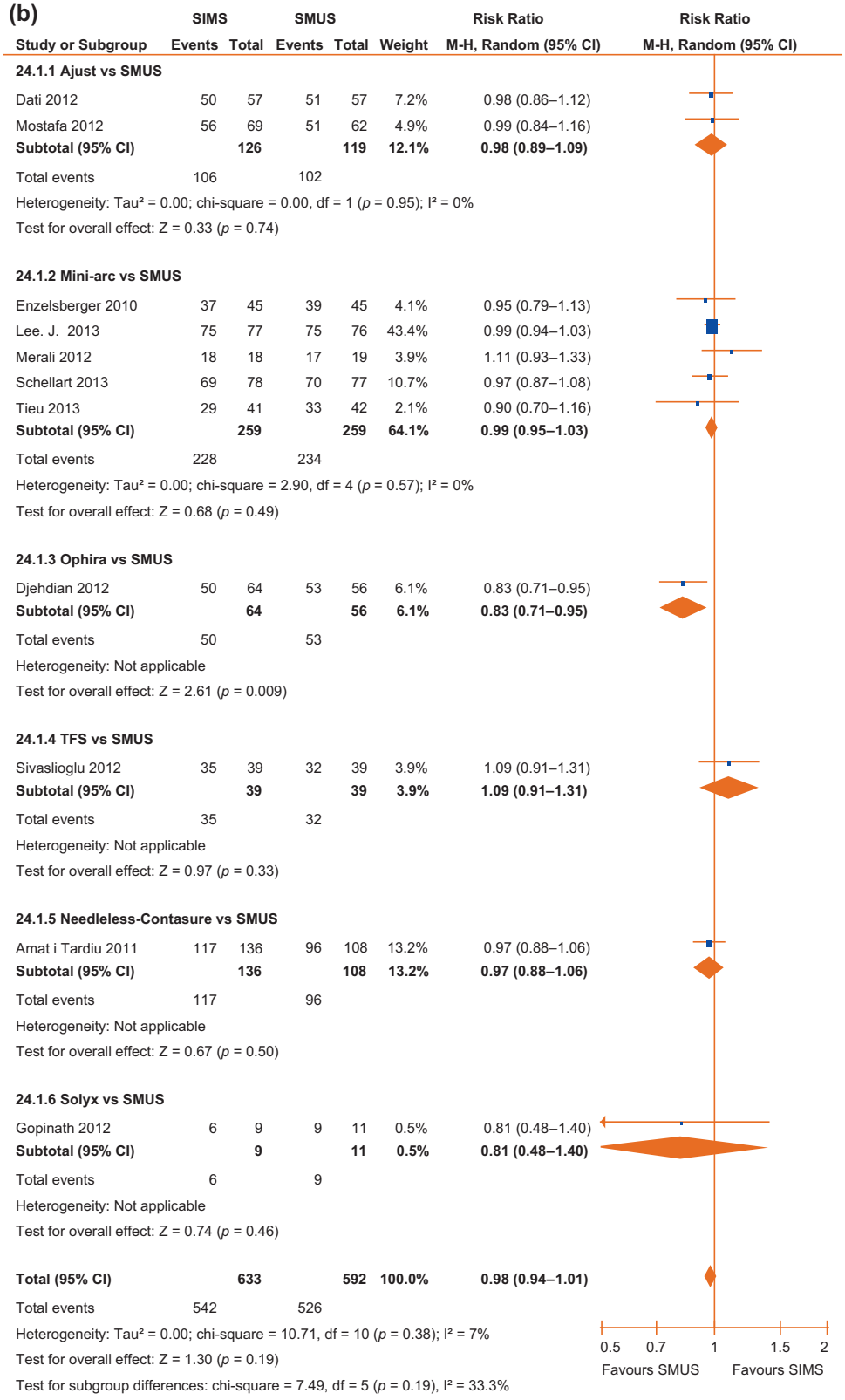


Fig. 2 – Cure rates: (a) Patient-reported cure rate; (b) objective cure rate; (c) patient-reported cure rate (vs retropubic-tension-free vaginal tape/ transobturator tension-free vaginal tape (RP-TVT/TO-TVT); (d) objective cure rate (vs RP-TVT/TO-TVT); (e) Patient-reported cure rate (TVT-Secur only); (f) objective cure rate (TVT-Secur only). CI = confidence interval; M-H = Mantel-Haenszel; SIMS = single-incision mini-sling; SMUS = standard midurethral sling; TFS = Tissue Fixation System.



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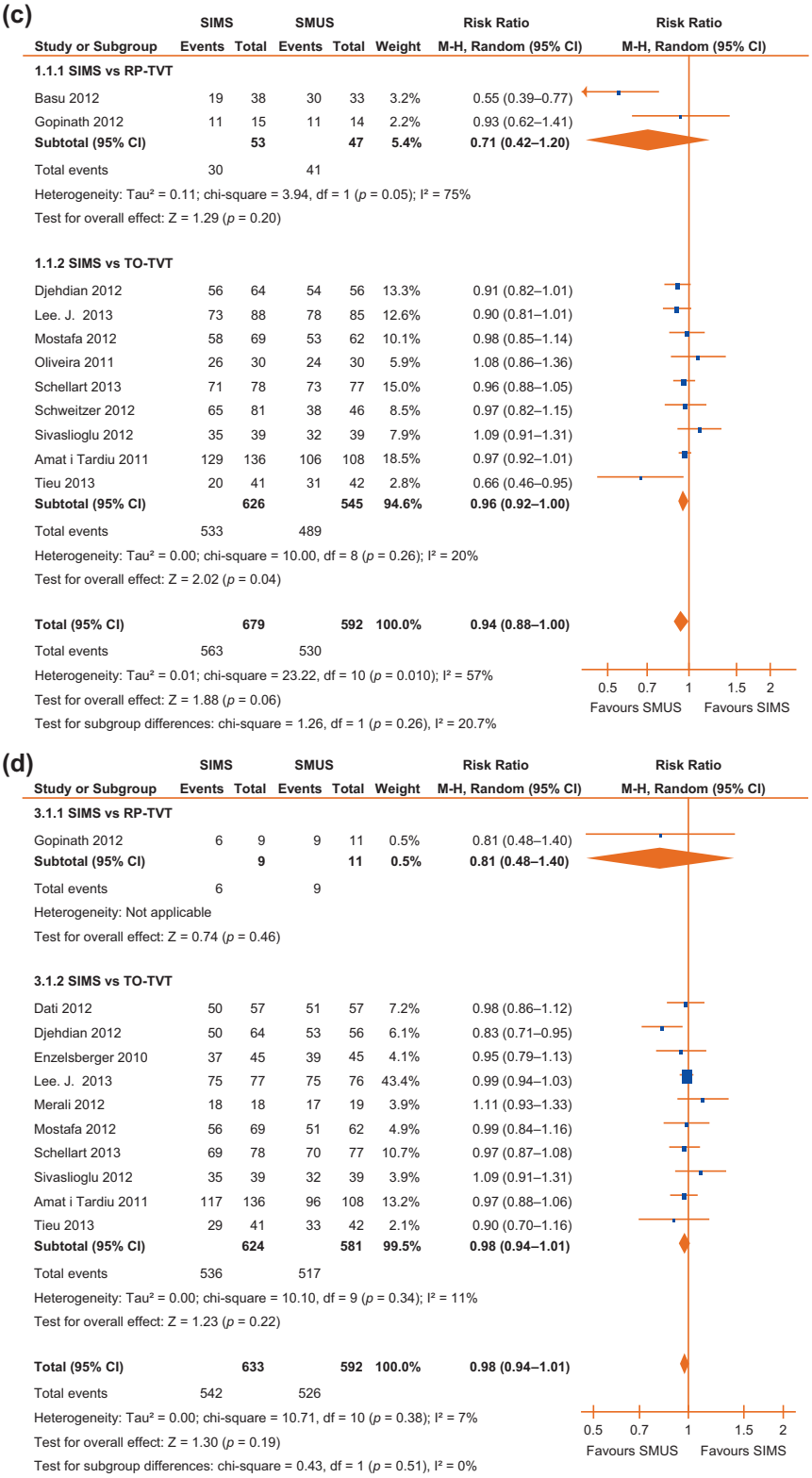

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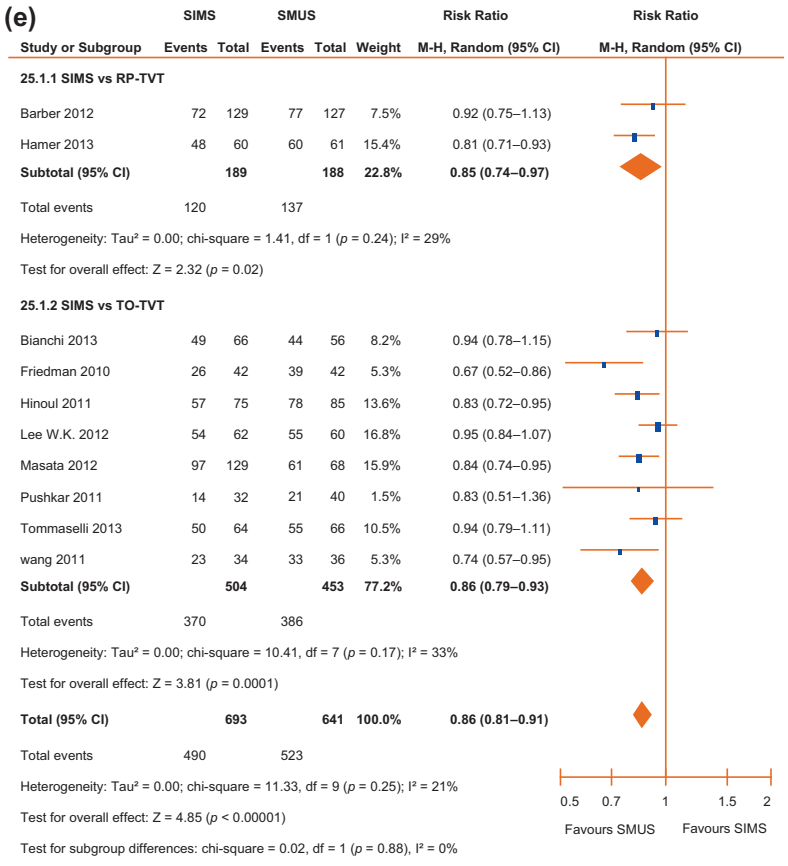

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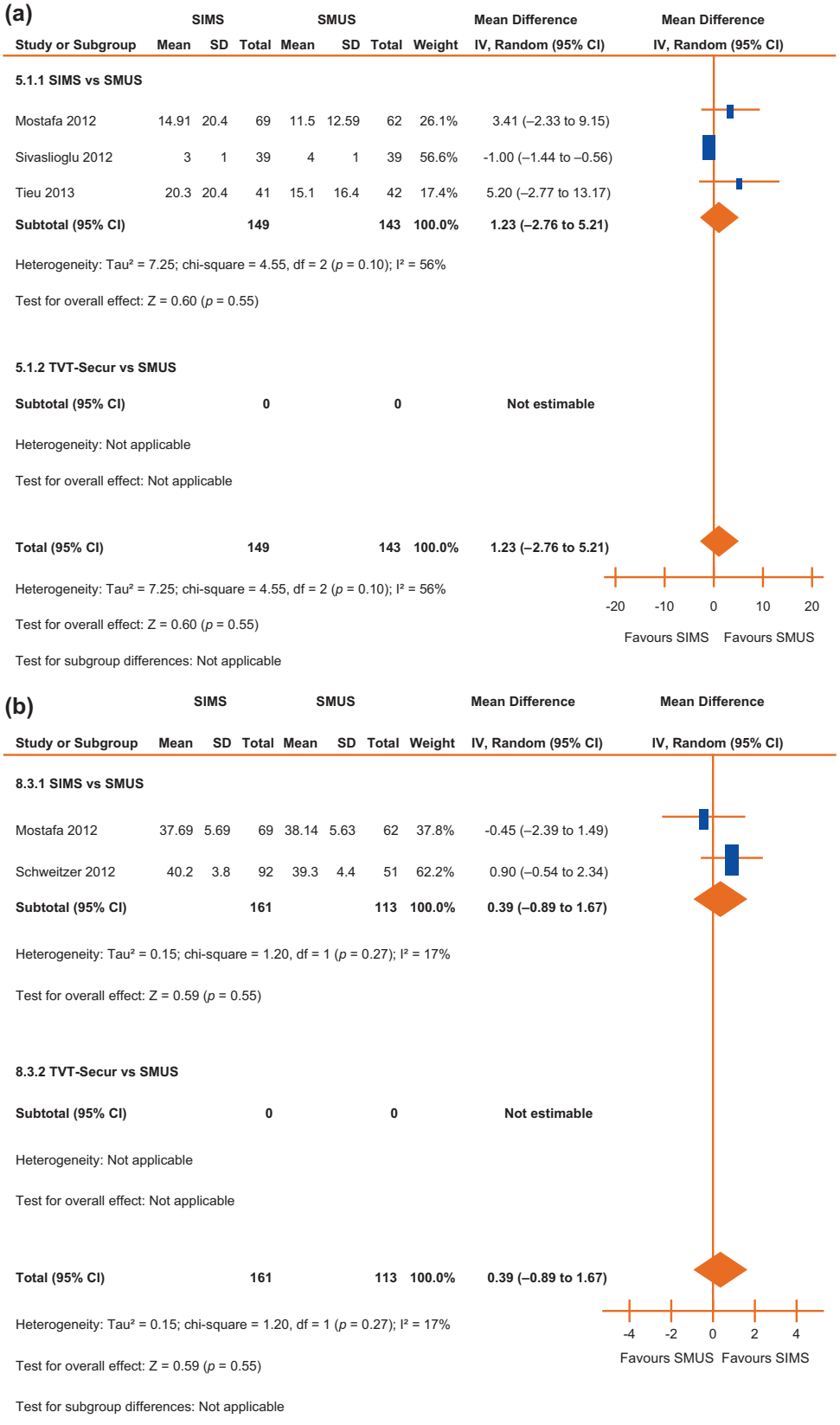


Fig. 3 – Quality of life (QoL): (a) QoL; (b) sexual function. CI = confidence interval; IV = inverse variance; SD = standard deviation; SIMS = single-incision mini-sling; SMUS = standard midurethral sling.

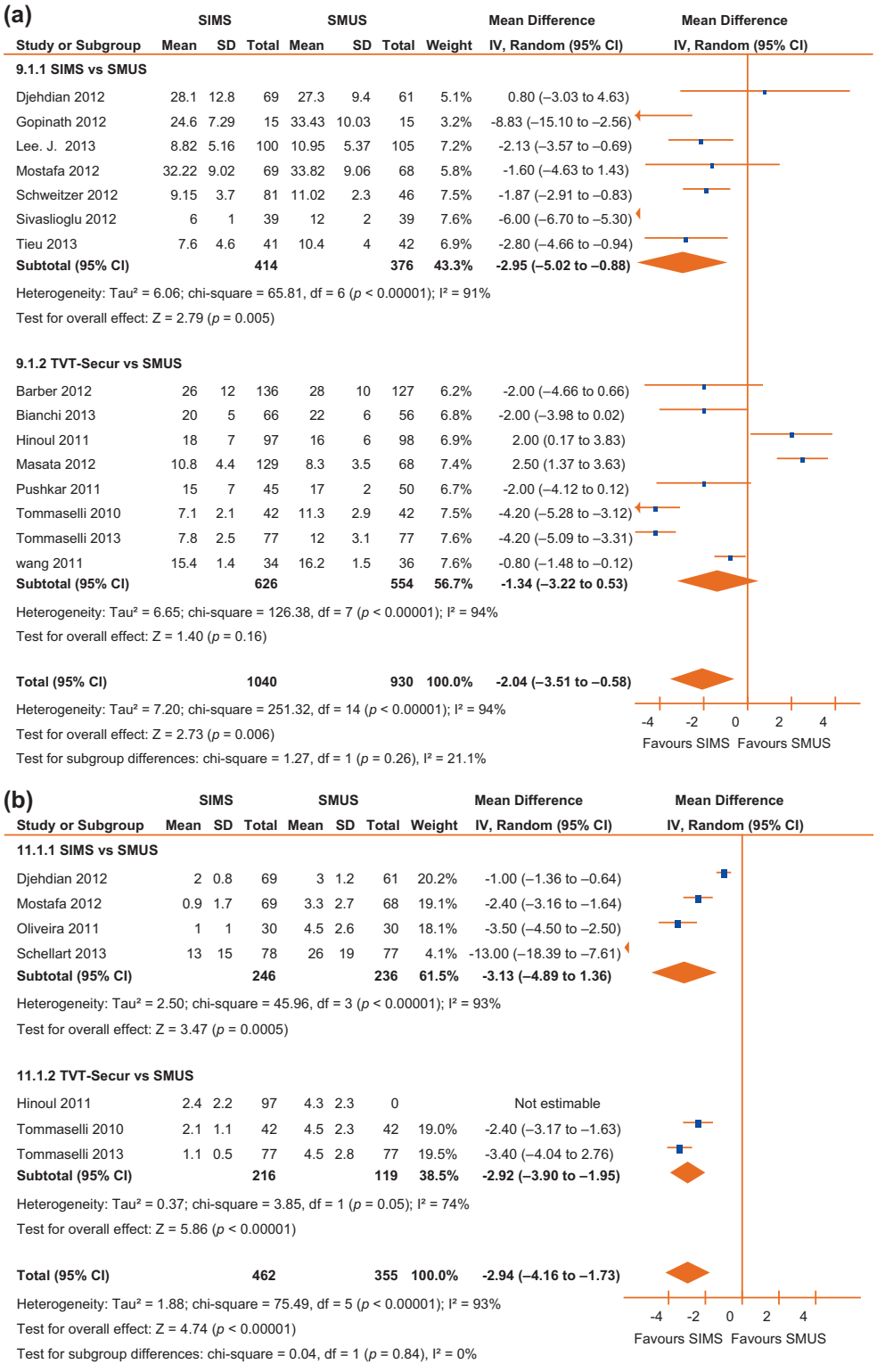
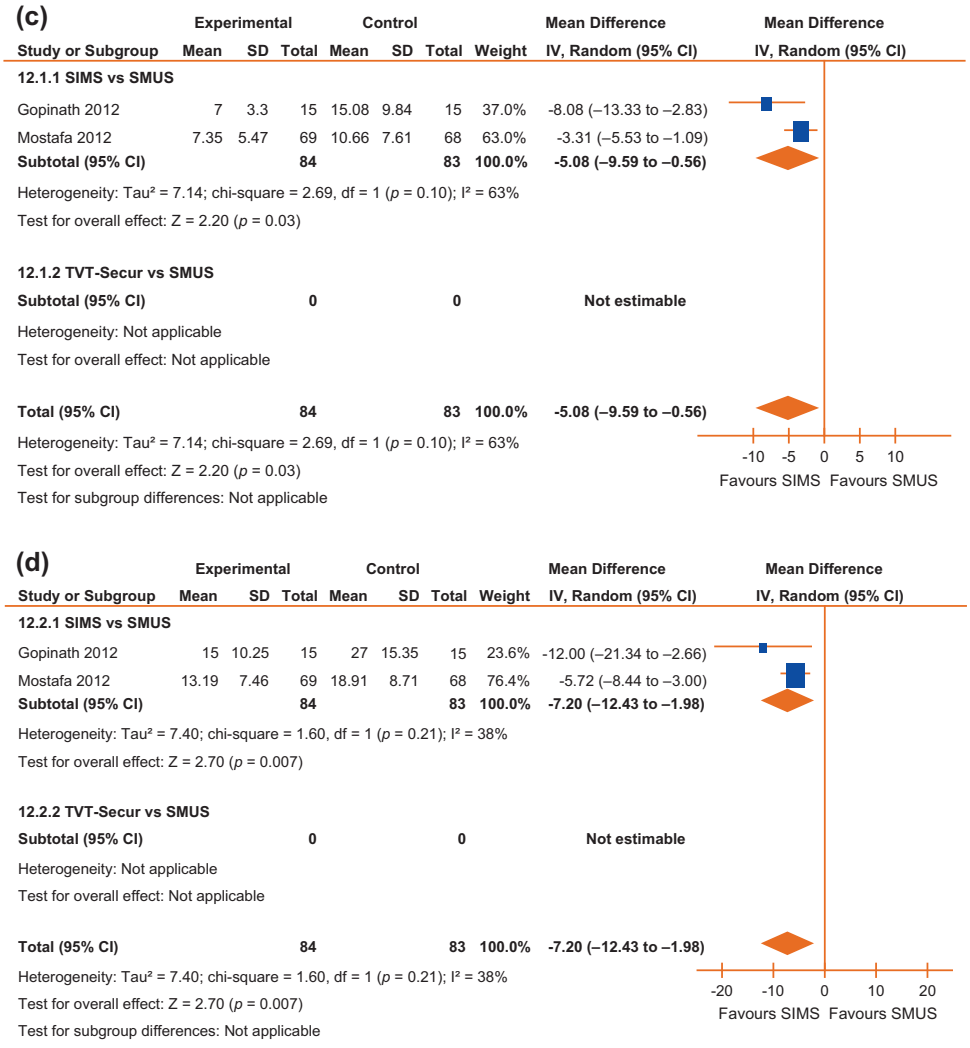


Fig. 4 – Operative data: (a) Operative time; (b) postoperative pain; (c) time to return to normal activities; (d) time to return to work. CI = confidence interval; SD = standard deviation; SIMS = single-incision mini-sling; SMUS = standard midurethral sling.



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3.5. *Heterogeneity*

No studies were excluded on the basis of methodological heterogeneity. There was a low estimate of statistical heterogeneity (<25%, as measured by the I^2 calculation) in objective cure rate, postoperative complications, and impact on sexual function. There was a moderate estimate of statistical heterogeneity (I^2 between 25% and 75%) in patient-reported cure rates, time to return to normal activity/work, and QoL. There was a high degree (>75%) of statistical heterogeneity in operation time and postoperative pain scores.

3.6. *Risk of bias*

The risk of bias was assessed using a risk-of-bias graph (Fig. 6). Most RCTs had good sequence generation and allocation concealment; however, reporting of blinding methods and rates of incomplete outcome data in most RCTs were generally poor. Two studies used a quasi-randomised method [12,23].

3.7. *Discussion*

The European guidelines [42] on the management of urinary incontinence describes two concepts of MUS for the surgical treatment of SUI in women: (1) Tension-free MUS that include all MUS that depend on their postinsertion fixation mechanism on friction to nearby tissues within their relatively long trajectory of insertion such as SMUS (both RP-TVT and TO-TVT); one type of nonanchored SIMS (Contasure-Needleless) also fits into this group. (2) Anchored MUS that include all other SIMS and other anchored slings such as Remeex TRT; the latter is mainly used in women with recurrent SUI [43,44]. SIMS fundamentally differs from SMUS because they have a shorter trajectory of insertion and therefore need a robust anchoring mechanism to the obturator complex with a strong postinsertion pullout force. All currently available SIMS share the same tape material (type 1 polypropylene) and the insertion technique through a single vaginal incision; however, they differ in the type/robustness of the anchorage mechanism used (45,46). A number of recently

developed SIMS have an added advantage that allow postanchorage adjustment of the sling tension.

We urged caution in interpretation of our meta-analysis in 2011 [1] because there was a limited number of single-centre underpowered RCTs, most of which had a significant risk of bias. Additionally, none of those RCTs assessed the recently developed adjustable and robustly anchored SIMS, such as Ajust, Altis, and TFS. These latter types of SIMS used different designs of polypropylene anchors that have been shown in independent animal studies, assessing their immediate and delayed extraction forces, to be associated with the strongest and most robust anchoring mechanism to the obturator complex [45,46]. We performed an exploratory subgroup analysis of four RCTs evaluating SIMS-Ajust and SIMS-TFS versus TO-TVT and found no evidence of significant differences in patient-reported or objective cure rates (Fig S3, S4). However, it is important to note that we found no RCTs evaluating Altis. Evidence of longer term outcomes for adjustable anchored SIMS is now emerging: Sivaslioglu et al. [24] recently reported the 5-yr follow-up for their RCT ($n = 80$) comparing adjustable anchored SIMS-TFS versus TO-TVT. The results showed significantly better objective success rates in the SIMS-TFS group (83% vs 75%; $p = 0.029$). Naumann et al. [47] recently reported their 29-mo follow-up for a prospective observational study of 51 women who underwent SIMS-Ajust and reported a patient-reported success rate of 86%.

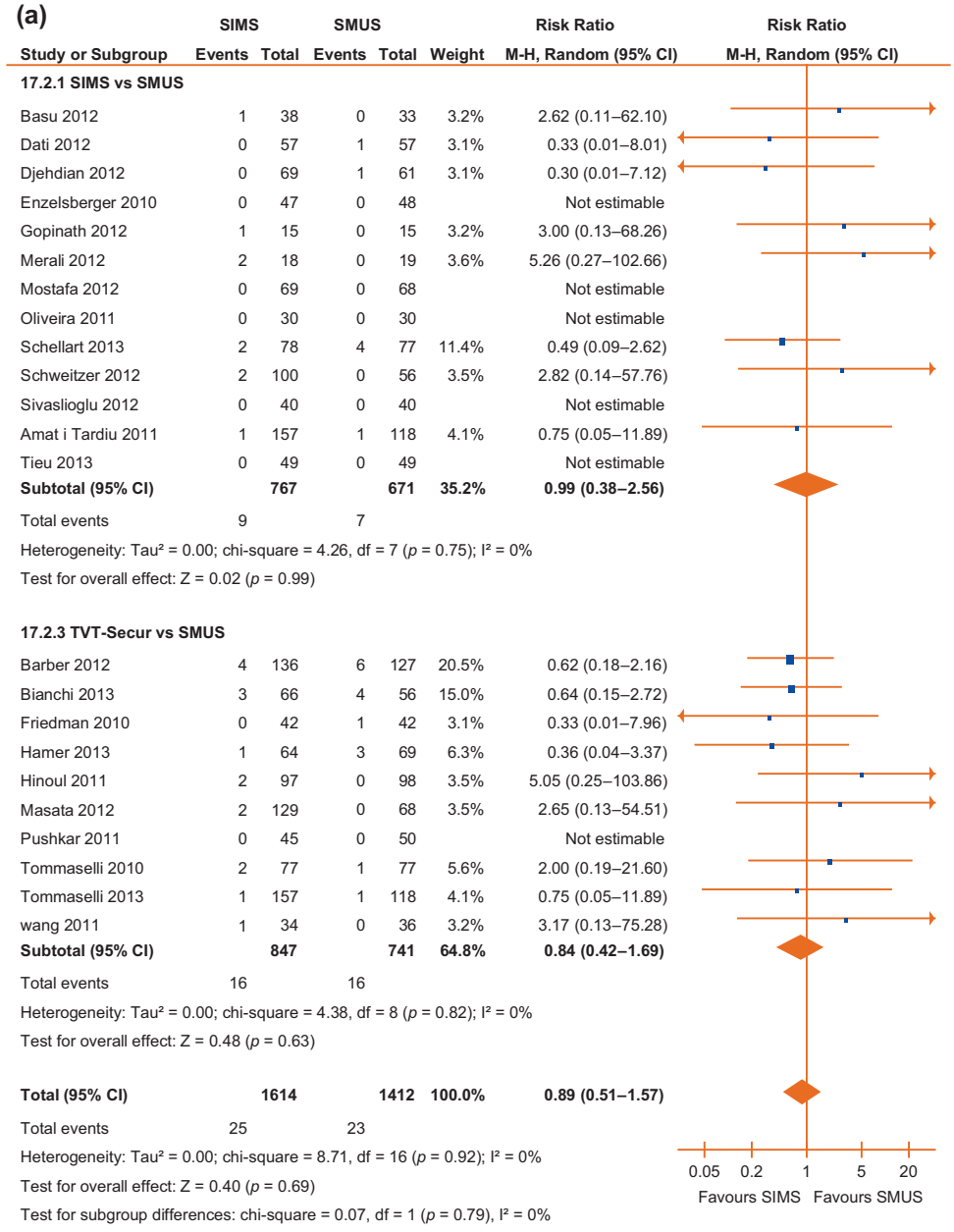
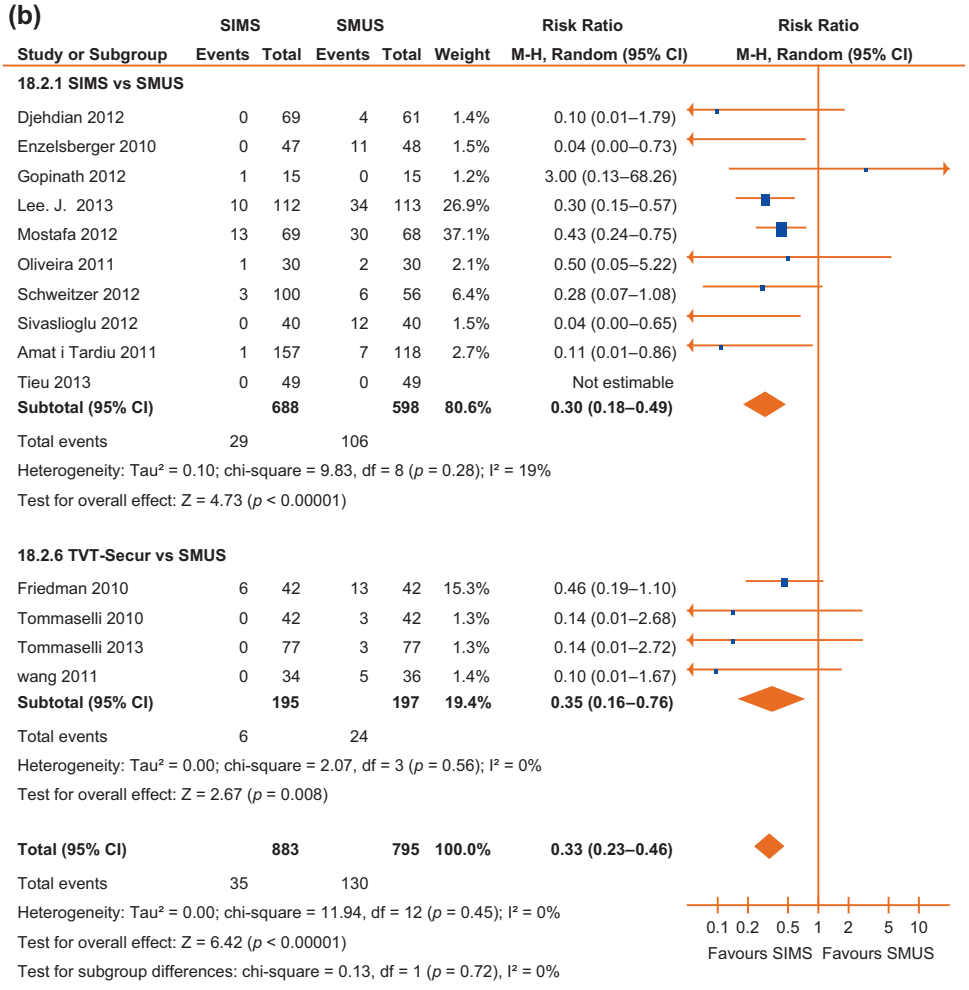


Fig. 5 – Perioperative complications: (a) Lower urinary tract injuries; (b) groin pain; (c) postoperative voiding difficulties; (d) de novo urgency and/or worsening of preexisting surgery; (e) vaginal tape erosion; (f) repeat continence surgery. CI = confidence interval; M-H = Mantel-Haenszel; SIMS = single-incision mini-sling; SMUS = standard midurethral sling.



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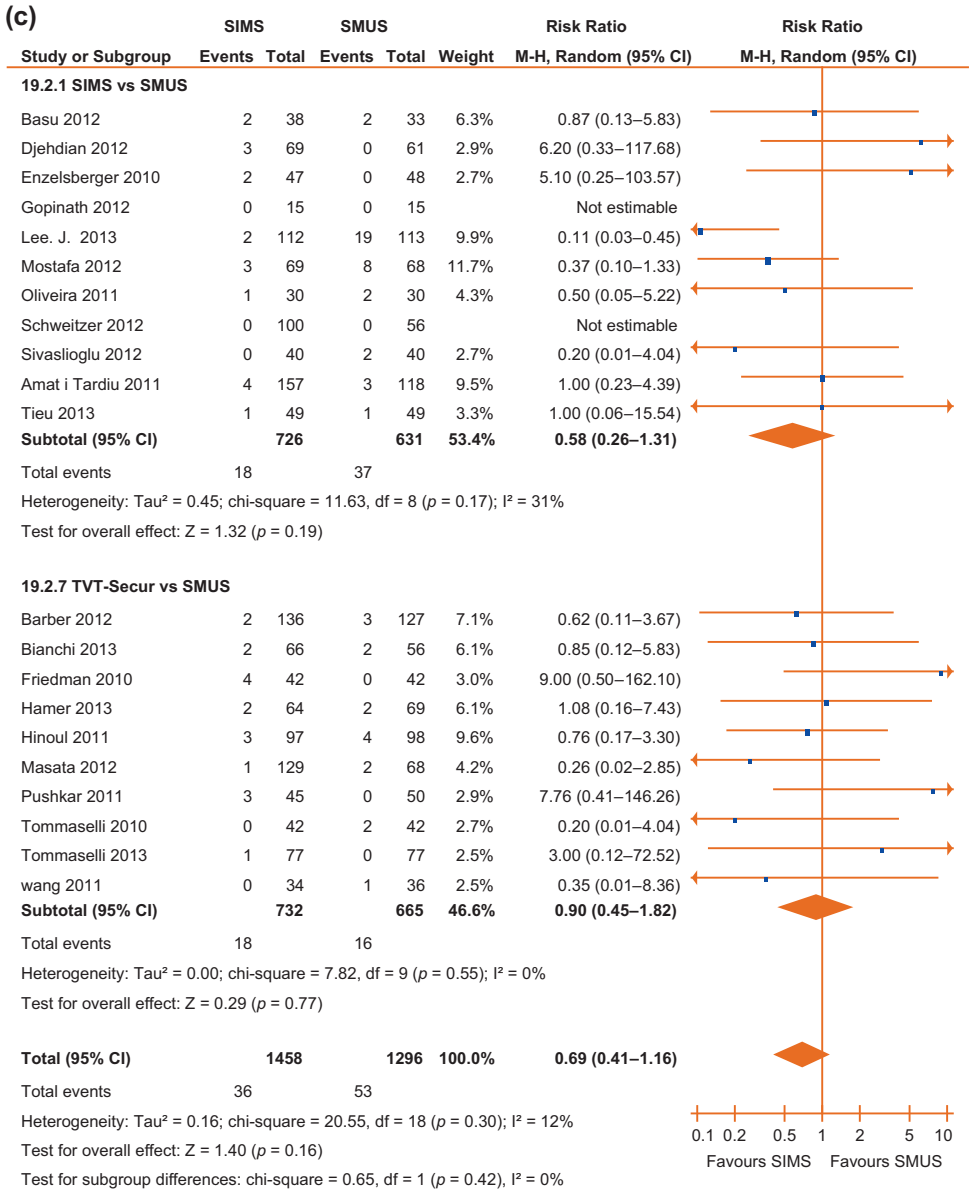

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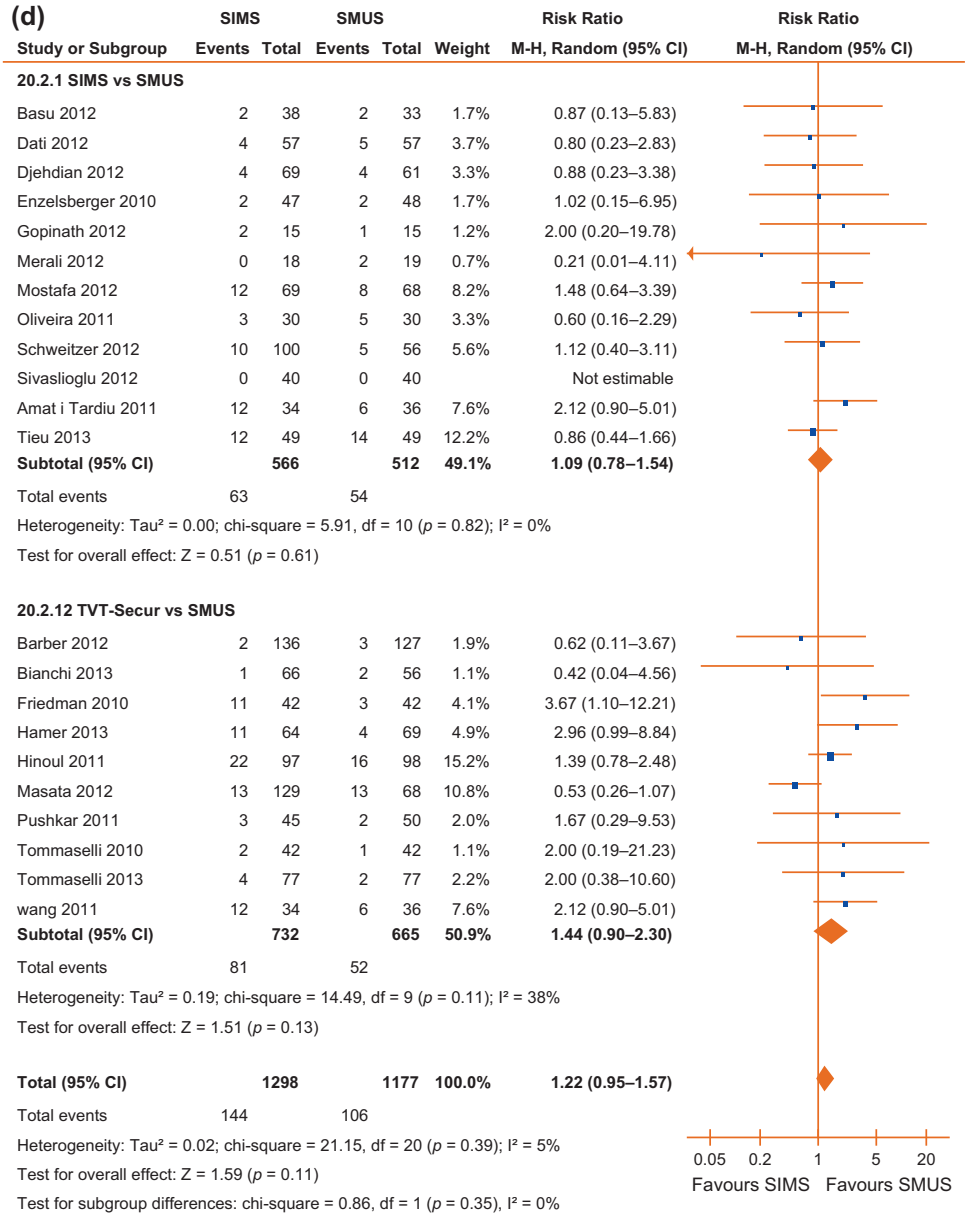

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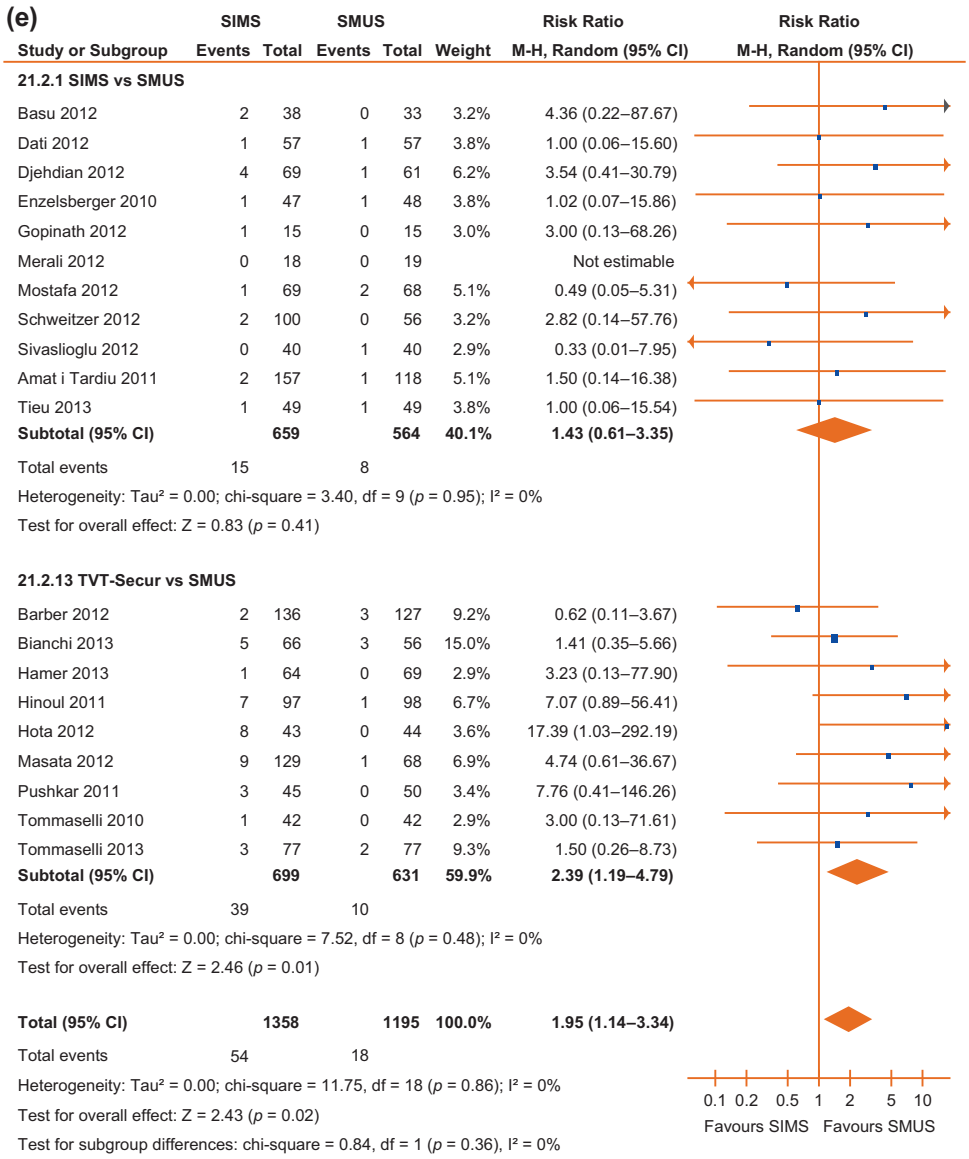

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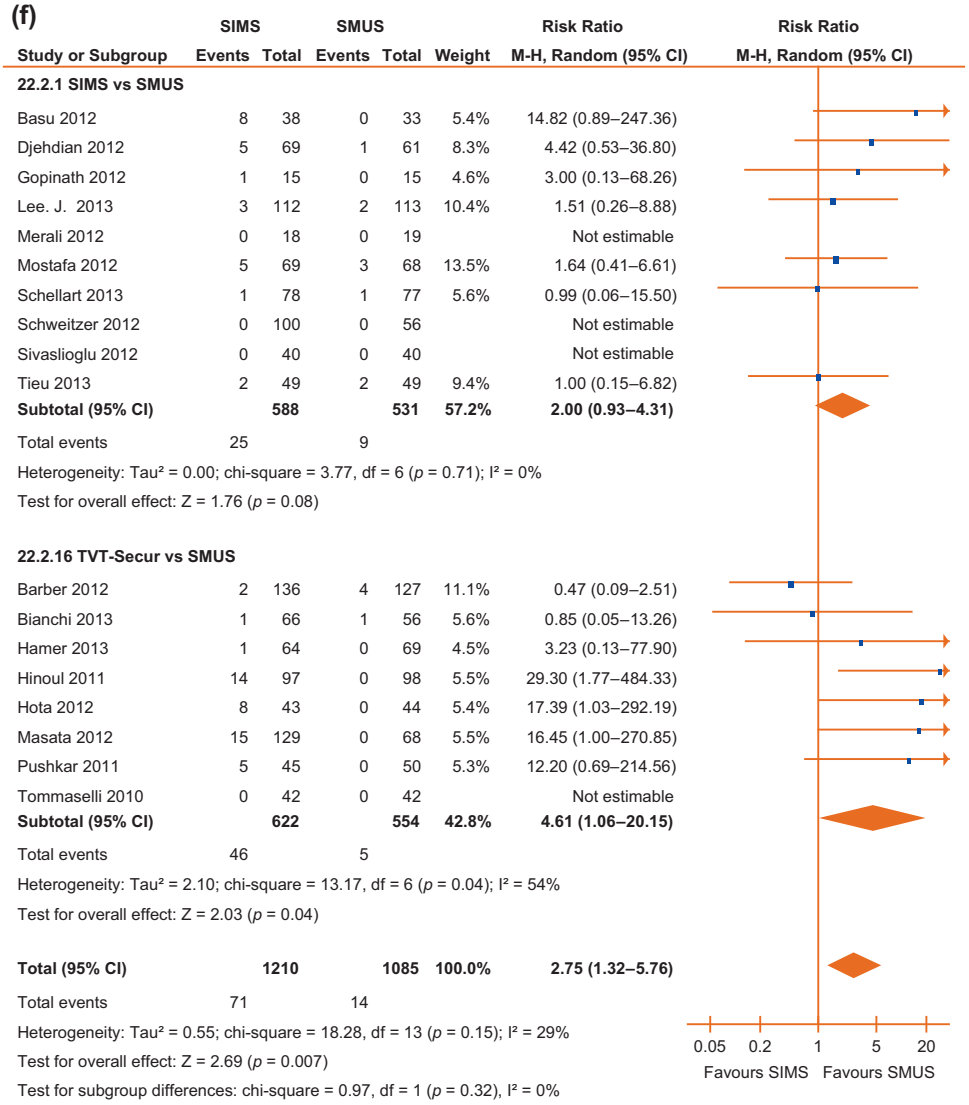

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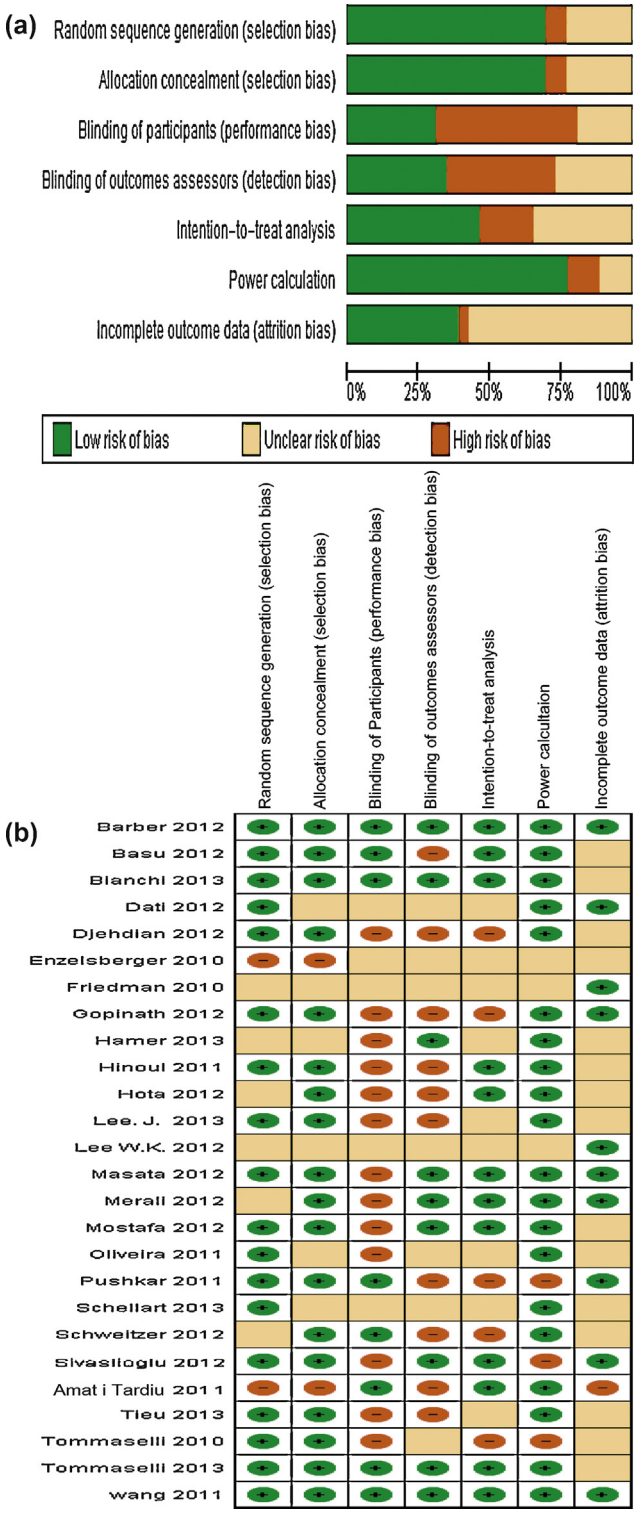

Fig. 6 – Risk of bias.

Mini-arc is another SIMS using polypropylene anchors that was designed to withstand a strong pullout force (four times the normal pelvic floor strain (5.75 lbs) [48]; however, animal studies showed their anchoring mechanism to be relatively weak compared with other SIMS [46]. The evidence with regard to its clinical effectiveness is conflicting with two RCTs showing clear inferior patient-reported cure rates in the Mini-arc group (Fig. 2); however, meta-analyses of all five RCTs showed a nonsignificant trend towards lower patient-reported cure rates. MiniArc Precise is the newer version with exactly the same criteria, but it is designed to be more stable during insertion and

provide more room for postinsertion adjustability. There is clear lack of evidence regarding the MiniArc Precise, which has been promoted as having a simpler insertion technique and allowing a relatively higher degree of postinsertion adjustability compared to the original MiniArc. Solyx SIMS has a similar design to MiniArc; we found only one RCT comparing Solyx with RP-TVT; however, the numbers in each group are very small ($n = 15$), consistent with a pilot RCT, and therefore no conclusion can be drawn regarding its clinical efficacy.

Other types of SIMS do not use polypropylene anchors. Contasure-Needleless uses "fascial pockets" on both ends, and conventional surgical forceps are used as introducers. Ophira has integral multiple fixation points projecting from the tape (except at the suburethral portion) and a loosening suture; it was thought to provide more stabilisation and stronger fixation; however, this failed to be demonstrated in independent animal models [46]. Ophira showed significantly inferior objective cure rates when compared with SMUS; however, no significant difference was seen in the patient-reported outcomes. One single-centre RCT compared each of Contasure-Needleless and Ophira versus SMUS, and therefore the results have to be interpreted with caution having not been reproduced in other RCTs or a multicentre setting.

Unlike other SIMS, TVT-Secur has a "Velcro-style secure tip" formed of a combination of absorbable and nonabsorbable fixation tips with no real anchorage mechanism. Our meta-analysis of RCTs ($n = 10$) evaluating TVT-Secur confirmed clear and significantly poor outcomes compared with SMUS. These findings agree with a number of observational studies with 2–3 yr of follow-up [4–7]. In response to the accumulating evidence, the manufacturer (Ethicon) recently announced the withdrawal of TVT-Secur from current practice, in effect from March 2013 [3]. It was therefore expected that on excluding RCTs evaluating TVT-Secur, the comparison of the rest of SIMS to SMUS would became more favourable. It was reassuring to see that these promising outcomes pertained to the analysis of SIMS versus RP-TVT and TO-TVT separately. Interestingly, despite the exclusion of TVT-Secur, SIMS still had a trend, albeit insignificant, towards higher rates of repeat continence surgery. The failure to show statistical significance may well be a type 2 error secondary to the small numbers of women requiring repeat surgery. It will be imperative to monitor this particular outcome on the longer-term follow-up.

In this updated meta-analyses, the previous favourable operative and recovery outcomes associated with the SIMS were confirmed. Despite being statistically significant, the shorter operative time (WMD: 2.95 min) is unlikely to be clinically significant. In addition, a high degree of heterogeneity between the included studies was noted. Similarly, the lower postoperative pain scores are only reported by most RCTs on day 1, which again casts doubt on its clinical significance. Interestingly, one RCT [49] was adequately powered to show significant differences in postoperative pain and showed an improved postoperative pain profile up to 4 wk postoperative. SIMS were associated with a significantly earlier return to normal activities (WMD: −5.08 d) and to work (WMD −7.20), both of which are likely to have a positive impact on the wider community and economy. It is important to note that these outcomes were only reported in two RCTs. These results were not reflected in a better improvement in women's QoL in the SIMS group. This could be due to the late assessment of QoL changes at a few months postoperative or the relative insensitivity of current QoL assessment tools to predict this particular difference. Alternatively, earlier return to work may not be relevant to women's QoL in the UK, and future qualitative research may improve our understanding of women's expectations and priorities.

It was reassuring to see that no evidence of significant differences in most perioperative complications between both groups after excluding TVT-Secur. Nonsignificant trends towards less postoperative voiding dysfunction, more de novo urgency, and/or worsening of preexisting urgency were seen within the SIMS group. It was previously hypothesised that positioning the SIMS in close contact with the urethra may lead to increased postoperative irritation symptoms.

The cost effectiveness of any new technology is a prerequisite for its adoption in clinical practice; one RCT examined the health economic analysis of SIMS-Ajust versus SMUS-TVT-O [41]; the outcome measures were incremental costs to the health services, patient quality-adjusted life-years (QALYs), and incremental cost per QALY. The results showed that SIMS performed under LA delivered cost savings to a health service provider when compared with SMUS TVT-O and was likely to be cost effective up to 1-yr follow-up. The cost savings were derived by the lower resources required with pure LA procedures and the earlier return to work within the SIMS group. These results have not been reported by any other RCT and therefore require more confirmatory health economic analysis alongside a definitive noninferiority RCT with longer term follow-up.

The quality of any systematic review depends on the quality of the RCTs and the completion of the data sets. Most of the included RCTs (17 of 26) in this review had good sequence generation and allocation concealment, a more positive finding than the reported literature by Hall et al., who showed that only 25% of surgical RCTs report the randomisation process [50]. A clear strength in this updated meta-analysis is the inclusion of all RCTs in this field, whether published as an article or an abstract, with emphasis on the clinically relevant results. Some may argue that inclusion of RCTs that did not exclude women with concomitant prolapse surgery can be a limitation due to possible difference in cure rates for MUS when done as a sole procedure versus with concomitant prolapse repair. This is not a concern in the meta-analysis of RCTs because the difference in cure rates, if they exist, would have been taken care of within the randomisation of individual RCTs unless sizeable groups of these women have consistently fallen into one specific arm. There is no evidence that this was the case in this meta-analysis. In fact, inclusion of women with concomitant prolapse repair adds to the generalisability of the results for patients and clinicians.

We acknowledge a number of limitations: Lack of blinding in the RCTs can be a source of bias [51]. The participants blinding methods were poorly documented with only two RCTs reported performing sham incisions. Blinding of assessors was also poor (9 of 26 RCTs); these findings were lower than those reported in the current literature. Hall et al. showed that 50% of the surgical RCTs report blinding procedures [50]. Incomplete outcome data can also be a source of bias (attrition bias): 10 of 26 RCTs had complete outcomes data and/or reported the reasons for the loss of follow-up. Attrition bias is known to be common in surgical trials, especially with mid- to long-term follow-up [52,53]. We have adopted a clear strategy to overcome these potential limitations. We contacted all authors requesting the missing data, and we are in debt to them for their excellent response. Sensitivity analyses were performed for primary outcomes, including only high-quality RCTs. Another potential limitation was the level of heterogeneity secondary to different types of SIMS in this review. In response, we used the random-effects model throughout the meta-analysis and asked authors to provide their 24-mo results, if available, to reduce statistical heterogeneity. We also applied subgroup meta-analyses to evaluate every type of SIMS individually versus SMUS, which is more clinically relevant. The midterm follow-up duration of a mean of 18.6 mo is a potential limitation, and there is a risk of repeating the TVT-Secur outcomes. Therefore we are planning to further update this review in 2–3 yr to capture the long-term outcomes.

4. Conclusions

Our meta-analysis shows that, on excluding TVT-Secur, there was no evidence of significant difference in patient-reported cure, objective cure, impact on women's QoL, and sexual function between the currently used SIMS and SMUS with a mean of 18 mo of follow-up. SIMS were associated with a quicker postoperative recovery. The results have to be interpreted with caution due to the heterogeneity of the trials included. An adequately powered and carefully planned noninferiority RCT comparing the robustly anchored adjustable SIMS to SMUS, with 3-yr follow-up, is underway by the senior author to inform surgeons, patients, and decision makers with the most clinically effective, cost-effective surgical treatment for primary SUI.

Author contributions: Mohamed Abdel-Fattah had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Mostafa, Abdel-Fattah.
Acquisition of data: Mostafa, Lim, Hopper.
Analysis and interpretation of data: Abdel-Fattah, Mostafa, Madhuvrata.
Drafting of the manuscript: Mostafa, Abdel-Fattah.
Critical revision of the manuscript for important intellectual content: Abdel-Fattah, Madhuvrata, Lim, Hopper.
Statistical analysis: Mostafa.
Obtaining funding: None.
Administrative, technical, or material support: Mostafa.
Supervision: Abdel-Fattah.
Other (specify): None.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.eururo.2013.08.032.

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